

the patient in accordance with one of the personalized therapy programs or a preset  
BB clinician therapy program.

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#### REMARKS

The Office Action of November 7, 2002 has been carefully reviewed and this paper is responsive thereto. To summarize the status of this application claims 1-39 are pending in the application. The Office Action indicated that claims 9, 19, and 29 are objected to, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. The drawings and specification were objected for various informalities. Claims 15, 24, 30, and 31 are rejected for insufficient antecedent basis for various claim elements. Claim 30 is rejected as being indefinite for failing to particularly point out and directly claim the subject matter which applicant regards as the invention. Claims 1-8, 10-18, 20-28, and 30-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann (U.S. Patent Number 6,052,624, hereinafter 'Mann). Further claims 38 and 39 are rejected as being unpatentable over Mann in view of Wernicke et al. (U.S. Patent Number 5,231,988, hereinafter 'Wernicke).

By this response, Applicants have amended claims 1, 9-10, 15, 19-20, 23-24, and 29-31. No new matter has been introduced into the application. Attached hereto is a marked-up version of the changes by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

#### Allowable Subject Matter

The Office Action states that claims 9, 19, and 29 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The

Applicants would like to thank the Examiner for indicating the allowable subject matter of claims 9, 19, and 29. In response to the objection, Applicants have rewritten claims 9, 19, and 29 in independent form with all of the limitations of the base claims and any intervening claims. Therefore, Applicants respectfully submit that claims 9, 19, and 29 are in condition for allowance.

### **Drawings**

Applicants submit formal drawings along with the Amendment and Response to the Office Action to correct the informalities indicated on PTO form 948.

### **Specification**

The disclosure was objected to for certain informalities. In particular, the Office Action states that on page 15, line 10, beginning with the new sentence, “The patient programmer 50 comprises . . .” should be “The INS 5 comprises . . .”

Applicants have amended the disclosure to incorporate this change. Applicants, therefore, respectfully request withdrawal of the objection.

### **Rejection under 35 USC § 112**

Claims 15, 23, 24, 30, and 31 stand rejected under 35 U.S.C. § 112 for insufficient antecedent basis for various elements found in each of these claims. In particular, the Office Action states that claim 15 lacks antecedent basis for “the graphical display screen,” claim 23 lacks antecedent basis for “the computer instructions,” claim 30 lacks antecedent basis for “the means for creating, for storing and executing,” and claim 31 lacks antecedent basis for “the user.” In addition, claim 30 stands rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, Applicants have amended claims 15, 23, 24, 30, and 31 to address the Office Action rejections. The Applicants request withdrawal of the Office Action rejections in view of the Amendments.

### **Claim Rejections under 35 USC § 102**

Claims 1-8, 10-18, 20-28 and 30-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann. Though the Office Action quotes the language of 35 U.S.C. 102(b) in the rejection, Applicants have interpreted the rejection to be a 35 U.S.C. 102(e) rejection based on the Office Action statement following the quoted 102(b) paragraph. The Applicants respectfully traverse the rejection.

Mann discloses a method of programming electrode arrays having a multiplicity of electrodes using a directional input device such as a joystick. (Col. 4, Lines 35-47). The directional input device enables the user to adjust electrode configurations in order to “steer” the stimulation current such that the patient immediately feels the effect of electrode configuration changes. (Col. 4, Lines 47-51). The method allows for the programming of a tissue stimulator so that a desired pattern of tissue stimulation currents is applied to a selected group of electrodes that form part of the tissue stimulator. (Col. 8, Lines 17-23).

With regard to independent claim 1, Mann fails to disclose, teach, or suggest at least the element of “accessing at least two preset clinician therapy programs . . . .” In contrast to claim 1, Mann discloses altering a basic operating program by changing various parameters. Mann does not disclose “accessing at least two preset clinician therapy programs . . . .” to create at least one personalized therapy program. For at least this reason, it is respectfully submitted that claim 1 is patentably distinct over Mann.

Dependent claims 2-8 which depend from independent claim 1 are allowable for at least the same reason as independent claim 1.

With regard to independent claims 10, 20, and 30, Mann fails to disclose, teach, or suggest the ability to “create at least one personalized therapy program from the at least two preset clinician therapy programs.” In contrast to claims 10, 20, and 30, Mann discloses altering a single basic operating program by changing various parameters. For at least this reason, it is respectfully submitted that claims 10, 20, and 30 are patentably distinct over Mann. Dependent claims 11-18 and 21-28 which depend from independent claim 10 and 20, respectively, are allowable for at least the same reason as independent claims 10 and 20.

With regard to independent claim 31, Mann fails to disclose, teach, or suggest “a controller . . . wherein the patient can subsequently instruct the medical device via the patient programmer to provide therapy to the patient in accordance with one of the personalized therapy programs or a preset clinician therapy program.” In contrast to claim 31, Mann discloses only a single operating program such as a basic operating program. Mann does not provide a method wherein the patient can “subsequently instruct the medical device via the patient programmer to provide therapy to the patient in accordance with one of the personalized therapy programs or a preset clinician therapy program.” For at least this reason, it is respectfully submitted that claim 31 is patentably distinct over Mann. Dependent claims 32-39 which depend from independent claim 31 are allowable for at least the same reason as independent claim 31.

### **Claim Rejections under 35 USC § 103**

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann in view of Wernicke. Based on the above arguments, Applicants respectfully submit that claims 38 and 39 which depend from independent claim 31 are allowable for at least the same reason as independent claim 31.

### CONCLUSION

From the foregoing Amendments and Remarks, the Applicants respectfully submit that the above claims are in condition for allowance. Should there be any outstanding matters that might hinder allowance of the application, the Examiner is respectfully urged to contact the undersigned to arrange for a telephone interview.

Respectfully submitted,

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**Version with Markings to Show Changes Made**

**IN THE SPECIFICATION**

Paragraph beginning at line 10 of page 15 has been amended as follows:

--The INS 5 also uses telemetry 3 and 4 to communicate with the clinician programmer 40 or patient programmer 50. The [patient programmer 50] INS 5 comprises an INS controller 90, memory 100 and a telemetry block 80. The INS controller 90 processes instructions received at the telemetry block 80. In the preferred embodiment, the INS controller 90 will either download or upload data to or from the INS memory 100 depending on the instructions received at the telemetry block 80. The INS memory 100 includes memory sufficient for operation of the INS 5 and storage of all therapy programs. Those skilled in the art will appreciate that the INS memory 100 includes memory such as volatile Random Access Memory (RAM) such as Static RAM, nonvolatile Read Only Memory (ROM), and Electrically Erasable Programmable Read Only Memory (EEPROM) such as Flash EEPROM, as well as other suitable INS memory 100. Once the personalized therapy programs have been downloaded, upon instructions by the patient programmer 50, the INS controller 90 will be able to execute both the preset clinician therapy programs and the personalized therapy programs.--

**IN THE CLAIMS**

Claim 1 has been amended as follows:

1. (Amended) In a patient programmer, a method for patient-directed therapy management for a medical device comprised of:

accessing at least two [one] preset clinician therapy programs stored in the medical device;

creating at least one personalized therapy program from the accessed preset clinician therapy programs;

storing the personalized therapy program in the medical device; and

executing at least one personalized therapy program.

Claim 9 has been amended as follows:

9. (Amended) In a patient programmer, a method for patient-directed therapy management for a medical device comprised of:

accessing at least one preset clinician therapy program stored in the medical device;

creating at least one personalized therapy program from the accessed preset clinician therapy program, the personalized therapy program comprises at least one personalized therapy setting;

storing the personalized therapy program in the medical device;

executing at least one personalized therapy program; and

[The method for patient directed therapy management of claim 2] wherein the medical device is selected from the group consisting of a pacemaker, a defibrillator, a cochlear implant, an implantable diagnostic device, and an implantable pump.

Claim 10 has been amended as follows:

10. (Amended) A patient directed therapy management system comprising in combination:

a medical device comprising a telemetry block and memory with at least two [one] preset clinician therapy programs; and

a patient programmer comprising a telemetry block, the patient programmer able to [allow] create[ion of] at least one personalized therapy program from the at least two preset clinician therapy programs, the patient programmer further able to [and] store[age] and execute[ion of] the at least one personalized therapy program in the medical device.

Claim 15 has been amended as follows:

15. (Amended) The patient directed therapy management system of claim 13 or 14 wherein the patient uses [the] a graphical display screen and input medium to create and store the personalized therapy programs.

Claim 19 has been amended as follows:

19. (Amended) A patient directed therapy management system comprising in combination:

a medical device comprising a telemetry block and memory with at least one preset clinician therapy program;

a patient programmer comprising a telemetry block, the patient programmer able to allow creation of at least one personalized therapy program, and storage and execution of the at least one personalized therapy program in the medical device, wherein the personalized therapy program comprises at least one personalized therapy setting; and

[The patient directed therapy management system of claim 11] wherein the medical device is selected from the group consisting of a pacemaker, a defibrillator, a cochlear implant, an implantable diagnostic device, and an implantable pump.

Claim 20 has been amended as follows:

20. (Amended) A patient programmer for patient directed therapy management comprising in combination:

an input medium;

a telemetry block; and

a controller able to create at least one personalized therapy program from at least two preset clinician therapy programs, the controller able to [and] store the at least one personalized therapy program in a medical device.

Claim 23 has been amended as follows:

23. (Amended) The patient programmer of claim 21 wherein the [computer instructions] personalized therapy program executed by the patient programmer comprises [are] a personalized therapy algorithm.

Claim 24 has been amended as follows:

24. (Amended) The patient programmer of claim 21 wherein the [executed computer instructions are] personalized therapy program comprises a timing algorithm.

Claim 29 has been amended as follows:

29. (Amended) A patient programmer for patient directed therapy management comprising in combination:

an input medium;

a telemetry block;

a controller able to create at least one personalized therapy program and store the at least one personalized therapy program in a medical device, the personalized therapy program comprising at least one personalized therapy setting; and

[The patient directed therapy management system of claim 17] wherein the medical device is a medical device selected from the group consisting of a pacemaker, defibrillator, a cochlear implant, an implantable diagnostic devices, and an implantable pump.

Claim 30 has been amended as follows:

30. (Amended) A patient programmer comprising:

an input medium;

a programming means, connected to the input medium, for creating at least one personalized therapy program from at least two preset clinician therapy programs; and

a communication means, connected to the programming means [for creating], for storing and executing at least one personalized therapy program in a medical device.

Claim 31 has been amended as follows:

31. (Amended) A patient programmer for patient directed therapy management comprising in combination:

an input medium for receiving a plurality of personalized therapy settings from a patient,

wherein each personal therapy setting provide settings for a plurality of parameters of a therapy program selected from the group consisting of an amplitude, a pulse rate, a pulse width, a pulse frequency, an electrode polarity, and a directional sequence;

a telemetry block; and

a controller able to create a personalized therapy program for each personalized therapy setting received from the [user]patient and cause the personalized therapy programs to be stored in a medical device via the telemetry block, wherein the patient can subsequently instruct the medical device via the patient programmer to provide therapy to the patient in accordance with one of the personalized therapy programs or a preset clinician therapy program.